Prospective randomized controlled trial: Conventional versus powered phlebectomy

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Objectives: **Transilluminated powered phlebectomy (TriVex) is a new surgical technique that uses tumescent dissection, transillumination, and powered phlebectomy. The purpose of this study was to compare TriVex with conventional varicose vein surgery in terms of pain, cosmesis, recurrence, complications, and operating time.**

Methods: **One hundred eighty-eight limbs in 141 patients (33 men, 108 women; mean age, 42.5 years) with varicose veins were randomised to conventional (n = 100) or TriVex (n = 88). Exclusion criteria were venous ulceration or deep venous disease. Varicosities were graded with CEAP and clinical assessment (grades 1-3), and were similar in both groups. Randomization was single blinded. Long or short saphenous vein ligation or stripping was performed as indicated with duplex scanning. Operative time was from skin incision to leg bandaging. Phlebectomy was performed with conventional stab avulsions or TriVex. Patients completed assessment forms preoperatively and postoperatively (2, 6, 26, 52 weeks), and this was supplemented with physician clinical evaluation. Pain was assessed with visual analog score.**

Results: **There was a significant difference in the number of incisions for phlebectomy in the two groups (conventional, n = 29; TriVex, n = 5; $P < .0001$). TriVex was faster in the grade 3 (extensive) group, but this did not reach statistical significance. There was no difference in mean postoperative pain score over 8 days in the two groups ($P = .4624$). At 2 weeks there was no significant difference between the groups with regard to bruising ($P = .77$), cellulitis ($P = .33$), and numbness ($P = .33$). At 6 weeks there was no significant difference between the groups with regard to nerve injury ($P = .97$), residual veins ($P = .79$), cosmetic score ($P = .837$), and overall satisfaction ($P = .878$). At 6 and 12 months, there was no significant difference in cosmesis ($P = .955$, $P = .088$, respectively) or recurrence ($P = .27$, $P = .11$, respectively).**

Conclusions: **TriVex is a safe and effective method for excision of varicosities and compares well, after a learning curve, with conventional surgery in regard to complications and recurrence. It has the advantage of a trend toward reduced operating time in extensive varicosities, and significantly fewer incisions, although there was no perceived difference in cosmesis during follow-up. (J Vasc Surg 2004;39:88-94.)**

Treatment of varicose veins constitutes a major part of the workload of a vascular surgeon.[1] Although there are various treatment methods, surgery remains the standard therapy for symptomatic varicose veins.[2] In 1996 Dr Robert Muller described the technique of removing varicosities by using small skin stab incisions and hook phlebectomy.[3,4] Although this technique has achieved worldwide usage and has yielded satisfactory results, it can be tedious to perform, and this can lead to missed varices, which, along with multiple incisions, can impair cosmetic results.

Transilluminated powered phlebectomy (TriVex) is a new surgical technique that combines endoscopic powered vein resection and ablation of superficial varicosities with tumescent anaesthesia and irrigated illumination.[5] The perceived advantages of this new technique are direct visualization of the vein to be avulsed and the removal of veins through only a few incisions, resulting in better cosmesis and minimizing the risk for missed veins. We prospectively compared TriVex with conventional varicose vein surgery, with reference to operative time, postoperative pain, complications, cosmesis, and recurrence.

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MATERIALS AND METHOD

Approval for the study was obtained from the Federated Dublin Voluntary Hospitals Joint Research Ethics Committee. Patients awaiting varicose vein surgery were sent an appointment time for a triage clinic and an information package containing detailed descriptions of conventional phlebectomy and TriVex. This information was supplemented at the triage clinic with direct interview, and patients were encouraged to discuss the diagnosis and surgical procedure. On the day of surgery consent was obtained from the patient, who had been fully informed of both procedures, and randomization to one or the other procedure was accomplished with a random number generator. Patients were not aware of which procedure they had undergone, although clever patients would know by looking at their legs once the bandages were removed. Patients were blinded from the treatment method throughout the study period.

All patients underwent venous duplex scanning, and reflux was defined as reverse flow for greater than 0.5 seconds. Disease was graded with the CEAP classification;

Table I. St James's Hospital classification

Grade	*Description*	*Type of surgery*			
		Conventional		*TriVex*	
		n	*%*	*n*	*%*
1	Varicosities below knee (operation time <1 hr)	16	16	19	21.6
2	Varicosities below and above knee, not extensive or below knee alone and extensive (operation time 1–2 hr)	60	60	47	53.4
3	Varicosities below and above knee and extensive (operation time >2 hr)	24	24	22	25

all patients had either class 2 or class 3 disease. There was no significant differences in distribution between the groups: class 2, conventional treatment, 61%, versus Trivex, 53.4%, and class 3, conventional treatment, 39%, versus Trivex, 46.6%. In addition, local classification (grades 1-3) was also used. This is an arbitrary classification based on severity of veins and projected operating time (Table I), and has been beneficial in previous waiting list initiatives at our hospital.[6] The exclusion criteria were deep venous insufficiency on duplex scan, active or healed venous ulceration, and recurrent varicose veins. The indications for surgery are illustrated in Table II.

All varicosities were marked preoperatively with an indelible marker. Stab incisions for conventional surgery are placed every 3 to 4 cm along the length of the varicosities for complete excision. This formed the basis of the incision count at the end of procedure. A record was made of the actual number of incisions made and the estimated number of incisions for the alternative procedure, whether TriVex or conventional surgery.

Surgical technique. Patients received prophylactic low molecular weight heparin (Clexane, 20 mg) preoperatively, and a single intravenous dose of antibiotic (Augmentin plus Co-Amoxiclav, 1.2 g) at induction. This is the standard protocol for all varicose vein surgery carried out at our institution. All of our patients are operated on as inpatients, and tend not to mobilize immediately. No patient had deep venous thrombosis, justifying our practice of routine prophylaxis. Antibiotic prophylaxis is the institution norm even for clean surgery, and this may explain why our incidence of wound infection is so low. All procedures were performed with the patient under general anesthesia. The saphenofemoral junction was approached through a standard 4-cm incision above the groin crease. The junction was clearly identified, and all tributaries were clipped and divided with a disposable clip applicator. The long saphenous vein and its duplication, if present, were stripped to the level of the knee with a disposable vein stripper. In patients requiring saphenopopliteal junction ligation the junction was marked preoperatively at duplex scanning. A transverse skin incision was made with the patient in the prone position, and the junction was clearly identified and ligated. In all patients the groin and popliteal incisions were infiltrated with 0.25% bupivacaine at the end of the procedure.

Table II. Indications for surgery

Symptoms	*Type of surgery*	
	TriVex	*Conventional*
Aches and pains	28	31
Bleeding	1	0
Heaviness or dragging	3	6
Itching	1	4
Phlebitis	2	0
Swelling	4	8
Unsightly veins	30	23

Thigh and calf varicosities were treated as per randomization. Conventional stab avulsions were performed through 2-mm incisions with an ophthalmic scalpel. Varady hooks were used to remove varices, which were then avulsed with a mosquito-toothed micro Halstead forceps (Aesculap, BH 119R).

TriVex was performed through 3-mm incisions with the protocol of Spitz et al.[5] The TriVex system consists of a combined irrigation-illumination wand (TCI; Smith & Nephew Endoscopy Division, Andover, Mass), a powered vein resector, a 300-W xenon light source, and a pressure infusion system. The illuminator has a bevelled tip set at 45 degrees, and is bi-channelled. One channel connects to the xenon light source, and the other connects to a pressure infusion system set at 700 mm Hg. The tumescent solution comprises 400 mg of lignocaine and 2 mL of 1:1000 adrenaline added to a liter of 0.9% saline solution. The powered resector has an inner rotary blade and a stationary sheath with a lateral window. The speed is set between 800 and 1000 rpm, and the device can function in three modes: forward, reverse, or oscillating. It also has two channels, one for infusing 0.9% saline solution under gravity, and the other connected to a conventional suction apparatus.

At the first stage of tumescence the illuminator is passed in the subcutaneous plane deep to and along the varicosities at the same time as infusion of the tumescent solution. This causes hydrodissection of the veins and increases the field of visualization. The resector is then passed through a similar incision placed in the same axis parallel to the illuminator. Both instruments work in unison; the illuminator is placed deeper to the resector, displaying the vein as a silhouette. The lateral window of the resector engages the vein with

suction, which is then morcellated and removed with the irrigation-suction system. Excision of the vein is completed with slow retraction of the handset along the line of the vein. Incisions for TriVex were strategically placed to remove maximal vein clusters within the arc of the instrumentation.

After resection of the varicosities, second-stage tumescent anaesthesia was instilled until the appearance of peau d'orange.[5] This minimized ecchymosis and hematoma formation. Groin and popliteal wounds were closed with deep and subcuticular sutures. Stab wounds were closed with steristrips. Crepe bandages were applied at the end of the procedure, and were replaced with thigh-length class I compression stockings at discharge.

A standardized leaflet containing detailed postoperative instructions was given to each patient. In addition, patients were advised to contact the department in case of complications.

Clinical data collection. Data collection was performed by completion of a series of simple questionnaires prepared to reflect the patients' objective and subjective symptoms, and these were supplemented with clinical examination by a physician. All patient responses were simplified by the use of a 10-point visual analog scoring system at 2 and 6 weeks, and 6 and 12 months postoperatively. Preoperative and follow-up data were entered into a database using Microsoft Access (Redmond, Wash).

Operative time was recorded from the time of groin or popliteal fossa incision to completion of application of bandages. When both the saphenofemoral and saphenopopliteal junctions were operated on, the time for surgery was the total time taken, including time for turning the patient. Overall time included setup time for TriVex instrumentation.

Statistical analysis. Appropriate statistical tests were used to compare the TriVex and conventional groups for the outcome variables. For highly skewed continuous data, such as pain scores, nonparametric tests (Mann-Whitney) were carried out. In the case of other quantitative data, analysis of variance or *t* tests were used. χ^2 and Fisher exact tests were used to compare the two groups in the case of count data. A power analysis was also conducted for the three major outcome variables, that is, duration of surgery, cosmetic score, and pain score at weeks 2 and 6. In each case a two-sided test with a significance level of 5% was used. The results indicated a power of 99% for the cosmetic score and pain scores at weeks 2 and 6 to detect a difference of 2 on the 10-point visual scale. The results for the duration of surgery suggested a power of 84% to detect a difference of 10 minutes.

RESULTS

During the study 201 patients were assessed for varicose vein surgery. Sixty patients were excluded from the study because of recurrent veins (n = 21), chronic venous insufficiency (n = 14), or refusal to participate (n = 25). One hundred eighty-eight procedures were performed in 141 patients (47 bilateral). There were 33 men and 108 women, with mean age of 42.5 years (range, 20-68 years). Saphenofemoral junction ligation and stripping of long saphenous vein was performed in 150 (79.9%) limbs (conventional, 82, vs TriVex, 68), and saphenopopliteal junction ligation and short saphenous vein avulsion in 14 (7.4%) limbs (conventional, 5, vs TriVex, 9). In an additional 14 (7.4%) limbs ligation of both the saphenofemoral and saphenopopliteal junctions was performed, in conjunction with long saphenous vein stripping and short saphenous vein avulsion (conventional, 8, vs TriVex, 6). Ten (5.3%) limbs underwent phlebectomy alone (conventional, 5, vs TriVex, 5). One hundred operations were performed in the conventional group, and 88 in the TriVex group. All limbs had either CEAP class 2 or 3 disease, with similar distribution in both groups. Table I illustrates the distribution of veins based on the local St James's Hospital classification. There was no significant difference between groups.

Table III. Operating time

Type of surgery	*Disease grade*	*Minimum (min)*	*Maximum (min)*	*Mean (min)*
Conventional	1	15	120	54.00
	2	15	150	63.55
	3	50	160	84.70*
TriVex	1	10	110	52.00
	2	15	120	66.08
	3	40	130	67.08*

*$P = .16$.

The mean number of actual incisions made for the conventional method was 29 ± 1.28 (range, 6-70), and the mean estimated number of incisions if TriVex had been used was 4 ± 0.15 (range, 2-8). The mean actual number of incisions for TriVex was 5 ± 0.17 (range, 2-8), and the estimated number if conventional surgery had been used was 28 ± 1.37 (range, 6-80). The number of incisions made in the TriVex group was significantly fewer ($P < .0001$).

Table III shows the operating time (in minutes) for each clinical grade in both groups. TriVex was approximately 18 minutes faster in treatment of grade 3 varicosities, although this did not reach statistical significance ($P = .16$).

The mean pain score was calculated from the visual analog pain scores at the end of postoperative weeks 1, 2, and 6. A score of zero signified "no pain," and a score of 10 signified the "worst possible pain." The mean pain scores are illustrated in Fig 1; there was no statistical difference between both groups. All patients were sent home with a standard prescription for analgesia (Celebrex, 200 mg once daily, and distalgesic, two tablets three times a day, for 1 week). We were unable to collect data on medication consumed, because patient compliance was poor.

Table IV illustrates complications, including cellulitis, cutaneous nerve injury, residual veins, and severe bruising, at 2 and 6 weeks postoperatively. At 2 weeks postoperatively, cellulitis was noted in three (3.00%) patients after

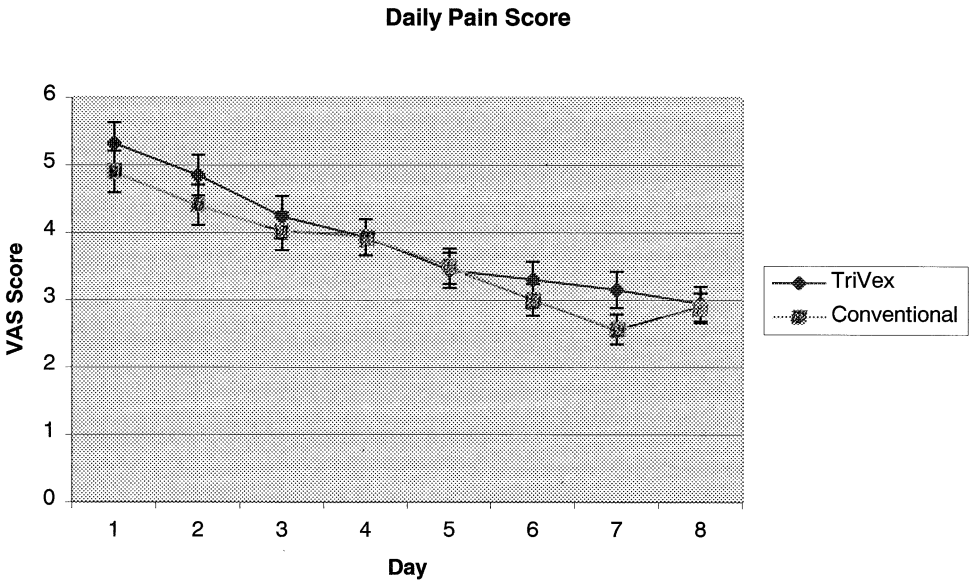

Fig 1. Daily pain scores.

Table IV. Complications

		Type of surgery				
		Conventional		*TriVex*		
Complication	*Postoperative week*	*n*	*%*	*n*	*%*	P
Cellulitis	2	3	3.0	2	2.3	.33
	6	0	0	0	0	
Cutaneous nerve injury	2	25	25.0	16	18.1	.33
	6	19	19.0	14	15.9	.97
	52	1	2.9	1	2.7	.99
Residual veins	2	3	3.0	6	6.8	
	6	8	8.0	8	9.1	.79
Severe Bruising	2	7	7.0	8	9.1	.77
	6	0	0	0	0	

conventional treatment, compared with two (2.3%) patients after TriVex ($P = .33$). These settled quickly with antibiotics, and no further treatment was required. Cutaneous nerve injury was defined as numbness and paresthesia, and occurred at 2 weeks in 25% and 18% of patients, respectively, who underwent conventional treatment or TriVex, and at 6 weeks in 19% and 16% of patients, respectively, after conventional or TriVex. At 1 year there was one residual cutaneous nerve injury in each group (3%). There were no major nerve injuries in either group.

At 2 weeks, residual veins were noted in three patients in the conventional group and six patients in the TriVex group. At 6 weeks this increased to eight patients in each group. Severe bruising occurred in 7.0% and 9.1% at 2 weeks postoperatively for the conventional and TriVex groups, respectively, and by 6 weeks postoperatively there was none in either group. No groin wound hematoma was recorded in either group, and there was no deep vein thrombosis. However, one patient had a calf hematoma, and required readmission. Statistically, there was no difference between the groups with regard to cellulitis, cutaneous nerve injury, severe bruising, or residual veins.

The cosmetic score was recorded at 6, 26, and 52 weeks. On the visual analog scale zero represents "worst possible result" imaginable, and 10 represents "best possible" cosmetic result. The number of limbs followed up after conventional surgery was 69 at 26 weeks and 34 at 52 weeks, compared with 57 limbs at 26 weeks and 37 at 52 weeks after TriVex. The mean cosmetic score for the conventional group was 8.27 ± 0.35, and for TriVex was 7.44 ± 0.38. There was no significant difference between the groups (Fig 2).

At 26 weeks there were six recurrences (of 69 limbs reviewed) in the conventional group, and six recurrences (of 57 limbs) in the TriVex group. At 52 weeks there were two recurrences (of 34 limbs reviewed) in the conventional group, and seven recurrences (of 37 limbs reviewed) in the TriVex group. All veins in the same initial area and also new

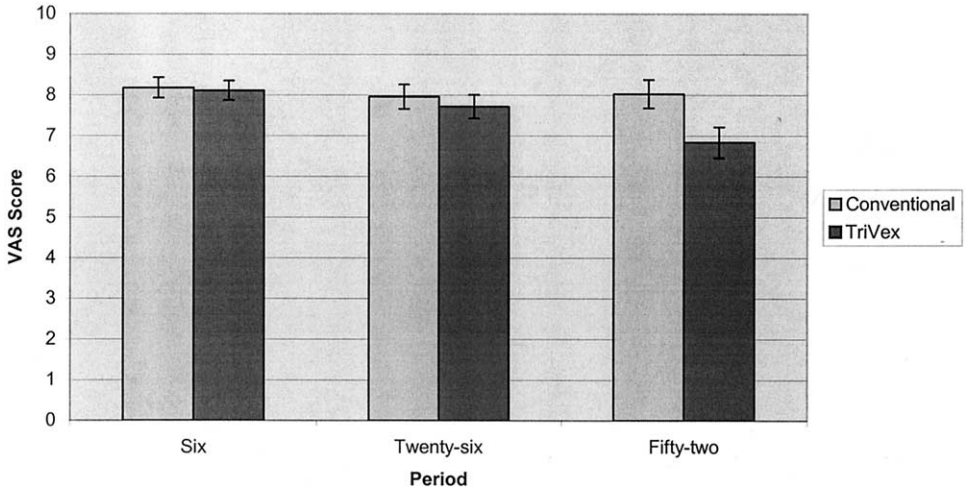

Fig 2. Cosmetic scores.

sources were classified as recurrences. There was only one recurrence at 52 weeks in the TriVex group if the first 20 cases were excluded from analysis, and two in the conventional group. All recurrences were in limbs with grade 3 disease, and there was no statistical significant difference between the groups.

Overall satisfaction for surgery, which was defined as a score of 8 or greater on the visual analog score, where zero represents "very dissatisfied" and 10 represents "very satisfied," was 91% and 87% at 6 weeks postoperatively for conventional and TriVex surgery, respectively. There was no statistical difference ($P = .878$) between groups. When asked "Would you recommend this operation to a friend?," 86.8% and 89.1% said "yes" and 13.2% and 10.9% said "no" for conventional and TriVex, respectively.

DISCUSSION

Several reports have confirmed the efficacy and safety of TriVex[5,7-10]; however, this study is the first published prospective comparative randomized trial comparing conventional varicose vein surgery with the new technique of powered phlebectomy (TriVex). Both groups were similar in terms of demographic data and extent of varices.

The number of incisions used in our TriVex group was similar to that reported by Spitz et al,[5] who first reported the use of this powered phlebectomy device. The number of incisions in our conventional group was greater than in their historical control group (28 vs 17). Spitz and colleagues had an incision ratio of approximately 3:1, and found a significantly better cosmetic result in their TriVex group. In contrast, we had an incision ratio of 7:1, and would have expected a better cosmetic result with TriVex. However, this was not the case; cosmesis was similar in both groups.

Our study did not show any difference in operating time for grades 1 and 2 varicosities, but the mean operating time was faster by approximately 18 minutes in grade 3 varicosities in the TriVex group, although this did not reach statistical significance. This is in contrast to the findings of Spitz et al,[5] who reported a mean operating time of 41 minutes for TriVex and 75 minutes for their control subjects, a difference of 34 minutes. This difference may be explained in that the operating time in our study included the set-up time for the TriVex instrumentation, and furthermore, the practice at our institution of having two surgeons working on a patient simultaneously. TriVex was faster by approximately 18 minutes in patients with extensive varicosities, and we are now looking at possible differences with single-surgeon surgery.

Assessment of pain scores showed no difference between groups. This supports the findings of others.[5,7-10] It is our policy to infiltrate groin and popliteal incisions with bupivacaine at the end of the procedure. Patients recorded their pain scores without differentiating pain from saphenofemoral junction or saphenopopliteal junction dissection sites, and no attempt was made to segregate these variables, because the entire procedure was assessed.

Cutaneous nerve injury associated with numbness and paresthesia occurred in 15.9% of TriVex limbs at 6 weeks, which is less than reported by Cheshire et al.[9] However, our reported incidence of cutaneous nerve injury of 19% in the conventional group is higher than in reported series.[11-13] At 1 year the incidence was significantly reduced, suggesting that most of these were neuropraxia. Permanent damage to cutaneous nerves was similar in both groups, and there were no major nerve injuries.

A high incidence of hematoma was reported in many series; Scavee et al[10] reported an incidence of 45% in their TriVex group and 25% after conventional phlebectomy. Their incidence of calf hematoma was 25% and 2.5% for TriVex and conventional surgery, respectively, but it is not clear how hematoma was defined. It is our opinion that our incidence of severe calf hematoma was low because of the introduction of a high-pressure infusion system for both primary and secondary tumescence. We reported severe bruising in 9.1% of the TriVex group and 7.0% of the conventional group at 2 weeks, but this had completely

resolved by 6 weeks in all patients. Our incidence of cellulitis was similar to that reported by Cheshire et al[9] in their TriVex group, and we found no difference in either group of our patients.

There was a higher number of recurrences in the TriVex group (21.2%; 7 of 33) compared with the conventional group (6.2%; 2 of 32) at 52 weeks postoperatively. However, six of these recurrences were in the first 20 TriVex procedures, which represents our early experience with the technique. We suggest that a longer familiarization period with the technique is necessary to obtain results superior to those of conventional surgery. Data analysis was begun after a learning curve that included 20 patients, and in hindsight this was insufficient to learn this new technique.

CONCLUSION

This study shows that TriVex is a safe and effective method for excision of varicosities. When performed by trained surgeons it has a comparable complication rate with that of conventional surgery. It has the advantage of a trend toward reduced operating time in extensive varicosities, and results in significantly fewer incisions, although there was no perceived difference in cosmesis during interval follow-up. The disposables used for the TriVex procedure amount to EUR 262 per patient (~$314). Despite the additional cost, we believe that TriVex has a definite place in treating varicose veins. when time and manpower are issues.

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DISCUSSION

Dr Peter R. Bell (Leicester, England). I don't think you really proved the last statement that you made, where you said powered phlebectomy was better than the conventional technique. There was no data to prove that.

Just a few questions. Who did the operations, experienced surgeons or juniors? Was the study blinded? Did you blind the assessors who decided on the cosmesis?

All this fluid you gave them, how many attacks of cardiac failure did you have?

What do you mean by neurapraxia? It's a huge incidence of neurapraxia. Where did it occur?

And you forgot one important element, the cost.

Dr Prakash Madhavan. I think we were very clear in the paper to say that, although there was a trend that TriVex was faster in patients with extensive varicosities, it did not reach statistical significance. In addition, in the Conclusion, all we have claimed is that there appears to be an advantage in using TriVex, especially in patients with extensive varicosities.

All patients are operated on by an experienced group of senior registrars and trainees with consultant supervision.

The patients were blinded to the treatment groups. They did not know what procedure they had undergone until the bandages were taken off.

There was no incidence of cardiac failure in the TriVex group.

With regard to neurapraxia, this was assessed by asking them a simple question: "Do you have any tingling or numbness in your leg?" The figures quoted are in the distribution of the saphenous and sural nerves. The apparently high incidence of nerve injury at first follow-up reduced to 3% at 1 year without any major nerve injuries.

Dr Robert B. McLafferty (Springfield, Ill). I was hoping that TriVex was going to show better results. I continually struggle with feeling the pressure to learn all these new technologies presented in our specialty, and now I realize I don't need to go out and learn something new. You have shown that conventional treatment is as good as TriVex.

A mean of 29 incisions for varicose veins seems awfully high for the conventional method. I wonder if there was bias in your study, knowing you were comparing TriVex with conventional treatment. I don't think I'd make that many incisions even in a leg with extensive varicose veins.

Dr Madhavan. Well, this was based on standard techniques that we use for conventional surgery. We actually validated this by looking at the number of incisions we used in patients before the trial. This would be the average number of incisions we would use for extensive varicose veins. This was based on a